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C. R. Bard, Inc. and
Bard Peripheral Vascular, Inc.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF ARIZONA

IN RE: Bard IVC Filters Products Liability MDL NO. 15-02641-PHX-DGC
Litigation

This Document Relates to:

KAREN BROWN,

Plaintiff,

Case No. CV-15-2302-PHX-DGC

v.

C. R. BARD, INC., a New Jersey
Corporation; AND BARD PERIPHERAL
VASCULAR INC., an Arizona
Corporation,

Defendants.

**DEFENDANTS C. R. BARD, INC. AND
BARD PERIPHERAL VASCULAR,
INC.'S ANSWER AND AFFIRMATIVE
DEFENSES AND DEMAND FOR
TRIAL BY JURY**

Defendants C. R. Bard, Inc. (“Bard”) and Bard Peripheral Vascular, Inc. (“BPV”) (Bard and BPV are collectively “Defendants”) answer the Complaint (“Plaintiff’s Complaint”) of Plaintiff Karen Brown (“Plaintiff”) as follows:

PARTIES

1. To the extent the allegations in Paragraph 1 of Plaintiff’s Complaint purport to cast liability upon Defendants, either directly or indirectly, those allegations are denied. Defendants are without information sufficient to form a belief as to the truth of the allegations regarding the trade name of any inferior vena cava filter implanted in Plaintiff and, on that basis, deny them. Defendants deny the remaining allegations contained in Paragraph 1 of Plaintiff’s Complaint.

2. Defendants deny the allegations contained in Paragraph 2 of Plaintiff’s Complaint.

3. Defendants admit that Bard is a New Jersey Corporation and that Bard is authorized to do business, and does business, in the State of Illinois. Defendants admit that Bard owns a facility where vena cava filters are manufactured, including filters under the trademark Eclipse™ Filter System. Defendants deny any remaining allegations contained in Paragraph 3 of Plaintiff’s Complaint.

4. Defendants admit that BPV is an Arizona Corporation and that BPV is authorized to do business, and does business, in the State of Illinois. Defendants further admit that BPV designs, sells, markets, and distributes inferior vena cava filters and that BPV has designed, sold, marketed, and distributed filters under the trademark Eclipse™ Filter System. Defendants further admit that BPV is a wholly owned subsidiary of Bard. Defendants deny any remaining allegations contained in Paragraph 4 of Plaintiff’s Complaint.

5. Paragraph 5 of Plaintiff’s Complaint does not include any factual allegations and, as a result, requires no response by Defendants. However, to the extent Paragraph 5 purports to cast liability either directly or indirectly upon Defendants, said Paragraph is expressly denied.

JURISDICTION AND VENUE

6. Defendants do not dispute that, based on the facts as alleged by Plaintiff, which have not been and could not have been confirmed by Defendants, jurisdiction appears to be proper in the United States District Court for the Northern District of Illinois. However, Defendants deny that they are liable to Plaintiff for any amount whatsoever and deny that Plaintiff has suffered any damages whatsoever.

7. Defendants do not dispute that, based on the facts as alleged by Plaintiff, which have not been and could not have been confirmed by Defendants, venue appears to be proper in the United States District Court for the Northern District of Illinois. Further, Defendants do not dispute that, based on the facts as alleged by Plaintiff, which have not been and could not have been confirmed by Defendants, jurisdiction appears to be proper in the United States District Court for the Northern District of Illinois. However, Defendants deny that they are liable to Plaintiff for any amount whatsoever and deny that Plaintiff has suffered any damages whatsoever.

ALLEGATIONS

8. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding the trade name of any inferior vena cava filter implanted in Plaintiff and, on that basis, deny them. Defendants deny the remaining allegations contained in Paragraph 8 of Plaintiff's Complaint.

9. Defendants admit that Bard designed, manufactured, and sold a device named the Eclipse™ Filter. Defendants admit that inferior vena cava filters are intended to prevent injury or death resulting from venous thrombosis and pulmonary embolism. Defendants further admit that BPV designs, sells, markets, and distributes inferior vena cava filters and that BPV designed, sold, marketed, and distributed filters under the trademark Eclipse™ Filter System. Defendants deny any remaining allegations contained in Paragraph 9 of Plaintiff's Complaint.

1 10. Defendants deny the allegations contained in Paragraph 10 of Plaintiff's
2 Complaint, including all sub-parts thereof.

3 11. Defendants lack knowledge or information sufficient to form a belief as to the
4 truth of the allegation regarding the time frame when inferior vena cava filters were first
5 introduced on the market or the identity of manufacturers of inferior vena cava filters.
6 Defendants deny any remaining allegations of Paragraph 11 of Plaintiff's Complaint.

7 12. Defendants admit that inferior vena cava filters are intended to prevent injury or
8 death resulting from venous thrombosis and pulmonary embolism. Defendants further admit
9 that inferior vena cava filters may be designed for permanent placement, temporary
10 placement, or both. Defendants deny any remaining allegations of Paragraph 12 of Plaintiff's
11 Complaint.

12 13. Defendants admit that the inferior vena cava is a large vein that receives blood
13 from the lower regions of the body and delivers it to the right atrium of the heart. Defendants
14 further admit that deep vein thrombosis and pulmonary emboli present dangerous risks to
15 human health, including sometimes death. Defendants deny any remaining allegations of
16 Paragraph 13 of Plaintiff's Complaint.

17 14. Defendants admit that certain people are at an increased risk for the
18 development of deep vein thrombosis and pulmonary embolus, but lack sufficient information
19 to form a belief as to the truth of the allegations as stated regarding the various risk factors
20 which may predispose an individual to deep vein thrombosis or pulmonary emboli and thus
21 deny them. Defendants deny any remaining allegations of Paragraph 14 of Plaintiff's
22 Complaint.

23 15. Defendants admit that patients at a high risk for developing deep vein
24 thrombosis and pulmonary embolism are frequently treated with anticoagulation therapy,
25 including but not limited to the medications listed in Paragraph 15 of Plaintiff's Complaint.
26 Defendants further admit that inferior vena cava filters may also be used to treat patients who
27 are at a high risk for developing deep vein thrombosis and pulmonary embolism. Defendants
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1 lack knowledge or information sufficient to form a belief as to the truth of any remaining
2 allegations contained in Paragraph 15 of Plaintiff's Complaint and, on that basis, deny them.

3 16. Defendants lack knowledge or information or information sufficient to form a
4 belief as to the truth of the allegation regarding the time frame when inferior vena cava filters
5 were first introduced on the market. Defendants also lack knowledge or information sufficient
6 to form a belief as to the truth of the allegation regarding the time frame when optional or
7 retrievable filters came to be marketed or the other allegations regarding optional or
8 retrievable filters marketed by other manufacturers. Defendants admit that the Recovery®
9 and Eclipse™ Filters were cleared by the FDA for optional use as retrievable inferior vena
10 cava filters. Defendants deny any remaining allegations contained in Paragraph 16 of
11 Plaintiff's Complaint.

12 17. Defendants admit that the Recovery® Filter was cleared by the FDA for
13 permanent placement on November 27, 2002, pursuant to an application submitted under
14 Section 510(k) of the Food, Drug and Cosmetic Act. The allegations pertaining to the
15 requirements of Section 510(k) contained in Footnote 1 are legal conclusions of law to which
16 no answer is required. Defendants deny any remaining allegations contained in Paragraph 17
17 of Plaintiff's Complaint, including any allegations contained in Footnote 1.

18 18. Defendants admit that the Recovery® Filter was cleared by the FDA for
19 retrievable placement on July 25, 2003, pursuant to an application submitted under Section
20 510(k) of the Food, Drug and Cosmetic Act. Defendants deny any remaining allegations
21 contained in Paragraph 18 of Plaintiff's Complaint.

22 19. Defendants deny the allegations contained in Paragraph 19 of Plaintiff's
23 Complaint.

24 20. Defendants admit that the Recovery® Filter consists of twelve, shape-memory
25 Nitinol wires emanating from a central Nitinol sleeve. Defendants further admit that the
26 twelve wires form two levels of filtration for emboli: the legs provide the lower level of
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1 filtration, and the arms provide the upper level of filtration. Defendants deny any remaining
2 allegations contained in Paragraph 20 of Plaintiff's Complaint.

3 21. Defendants admit that a nickel-titanium alloy named Nitinol is used in the
4 manufacture of the Recovery Filter and further admits that Nitinol contains shape memory.
5 However, to the extent Paragraph 21 purports to cast liability either directly or indirectly
6 upon Defendants, said Paragraph is expressly denied.

7 22. Defendants admit that the Recovery® Filter was designed to be inserted
8 endovascularly. Defendants further admit that the Recovery® Filter is designed to be
9 delivered via an introducer sheath, which is included in the delivery system for the device.
10 Defendants deny any remaining allegations of Paragraph 22 of Plaintiff's Complaint.

11 23. Defendants deny the allegations contained in Paragraph 23 of Plaintiff's
12 Complaint.

13 24. Defendants deny the allegations contained in Paragraph 24 of Plaintiff's
14 Complaint.

15 25. Defendants deny the allegations contained in Paragraph 25 of Plaintiff's
16 Complaint.

17 26. Defendants admit that there are various well-documented complications that
18 may occur as a result of the fracture, perforation, and/or migration of any inferior vena cava
19 filter. Defendants further admit that it is well documented that many instances of filter
20 fracture, perforation, and and/or migration result in no complications whatsoever but, rather,
21 are completely asymptomatic. By way of further response, Bard states that there are incidents
22 related to the occurrence of known complications associated with every manufacturer of
23 inferior vena cava filters. Defendants deny the remaining allegations of Paragraph 26 of
24 Plaintiff's Complaint.

25 27. Defendants deny the allegations contained in Paragraph 27 of Plaintiff's
26 Complaint.

1 28. Defendants deny the allegations contained in Paragraph 28 of Plaintiff's
2 Complaint.

3 29. Defendants deny the allegations contained in Paragraph 29 of Plaintiff's
4 Complaint.

5 30. Defendants admit that there are various well-documented complications that
6 may occur as a result of the fracture, perforation, tilt and/or migration of any inferior vena
7 cava filter. Defendants further admit that it is well documented that many instances of filter
8 fracture, perforation, tilt, and/or migration result in no complications whatsoever but, rather,
9 are completely asymptomatic. By way of further response, Bard states that there are incidents
10 related to the occurrence of known complications associated with every manufacturer of
11 inferior vena cava filters. Defendants deny the remaining allegations of Paragraph 30 of
12 Plaintiff's Complaint, including all sub-parts thereof.

13 31. Defendants deny the allegations contained in Paragraph 31 of Plaintiff's
14 Complaint.

15 32. Defendants deny the allegations contained in Paragraph 32 of Plaintiff's
16 Complaint.

17 33. Defendants deny the allegations contained in Paragraph 33 of Plaintiff's
18 Complaint.

19 34. Defendants admit that, as part of their continuing efforts to constantly evaluate
20 the medical devices they sell, in conjunction with the ever-changing state-of-the-art, they are
21 continually striving to improve the life-saving performance of those devices. The G2® Filter
22 was developed in furtherance of those efforts. Defendants deny the remaining allegations
23 contained in Paragraph 34 of Plaintiff's Complaint.

24 35. Defendants admit the G2® Filter System was cleared by the United States Food
25 and Drug Administration pursuant to an application submitted under Section 510(k) of the
26 Food, Drug and Cosmetic Act. Defendants admit that the G2® Filter was originally cleared
27 by the FDA for permanent use. Defendants further admit that the G2® Filter was
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1 subsequently cleared by the FDA for optional use as a retrievable inferior vena cava filter.
2 Defendants deny any remaining allegations contained in Paragraph 35 of Plaintiff's
3 Complaint, including those allegations contained in Footnote 2.

4 36. Defendants admit that, as part of their continuing efforts to constantly evaluate
5 the medical devices they sell, in conjunction with the ever-changing state-of-the-art, they are
6 continually striving to improve the life-saving performance of those devices. The G2® Filter
7 was developed in furtherance of those efforts. Defendants deny any remaining allegations of
8 Paragraph 36 of Plaintiff's Complaint.

9 37. Defendants deny the allegations contained in Paragraph 37 of Plaintiff's
10 Complaint.

11 38. Defendants deny the allegations contained in Paragraph 38 of Plaintiff's
12 Complaint.

13 39. Defendants admit that there are various well-documented complications that
14 may occur as a result of the fracture, perforation, tilt, and/or migration of any inferior vena
15 cava filter. Defendants further admit that it is well documented that many instances of filter
16 fracture, perforation, tilt, and/or migration result in no complications whatsoever but, rather,
17 are completely asymptomatic. By way of further response, Bard states that there are incidents
18 related to the occurrence of known complications associated with every manufacturer of
19 inferior vena cava filters. Defendants deny the remaining allegations of Paragraph 39 of
20 Plaintiff's Complaint, including all sub-parts thereof.

21 40. Defendants admit that there are various well-documented complications that
22 may occur as the result of the fracture, perforation, tilt, and/or migration of any inferior vena
23 cava filter. Bard states that there are incidents related to the occurrence of known
24 complications associated with every manufacturer of inferior vena cava filters. By way of
25 further response, Bard states that information available in the public domain, including the
26 FDA MAUDE database, is not a comprehensive analysis of all instances of such
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1 complications. Defendants deny the remaining allegations of Paragraph 40 of Plaintiff's
2 Complaint.

3 41. Defendants admit that there are various well-documented complications that
4 may occur as the result of the fracture, perforation, tilt, and/or migration of any inferior vena
5 cava filter. Bard states that there are incidents related to the occurrence of known
6 complications associated with every manufacturer of inferior vena cava filters. By way of
7 further response, Bard states that information available in the public domain, including the
8 FDA MAUDE database, is not a comprehensive analysis of all instances of such
9 complications. Defendants deny the remaining allegations of Paragraph 41 of Plaintiff's
10 Complaint.

11 42. Defendants admit the Eclipse™ Filter System was cleared by the United States
12 Food and Drug Administration pursuant to an application submitted under Section 510(k) of
13 the Food, Drug and Cosmetic Act in 2009. Defendants admit that, as part of their continuing
14 efforts to constantly evaluate the medical devices they sell, in conjunction with the ever-
15 changing state-of-the-art, they are continually striving to improve the life-saving performance
16 of those devices. The Eclipse™ Filter was developed in furtherance of those efforts.
17 Defendants deny any remaining allegations contained in Paragraph 42 of Plaintiffs'
18 Complaint.

19 43. Defendants admit that, as part of their continuing efforts to constantly evaluate
20 the medical devices they sell, in conjunction with the ever-changing state-of-the-art, they are
21 continually striving to improve the life-saving performance of those devices. The Eclipse™
22 Filter was developed in furtherance of those efforts. Defendants further admit that the
23 Eclipse™ Filter is constructed of Nitinol. Defendants deny any remaining allegations
24 contained in Paragraph 43 of Plaintiffs' Complaint.

25 44. Defendants deny the allegations contained in Paragraph 44 of Plaintiff's
26 Complaint.

1 45. Defendants deny the allegations contained in Paragraph 45 of Plaintiff's
2 Complaint.

3 46. Defendants deny the allegations contained in Paragraph 46 of Plaintiff's
4 Complaint, including all sub-parts thereof.

5 47. Defendants deny the allegations contained in Paragraph 47 of Plaintiff's
6 Complaint.

7 48. Defendants deny the allegations contained in Paragraph 48 of Plaintiff's
8 Complaint.

9 49. Defendants deny the allegations contained in Paragraph 49 of Plaintiff's
10 Complaint.

11 50. Defendants deny the allegations contained in Paragraph 50 of Plaintiff's
12 Complaint, including all sub-parts thereof.

13 51. Defendants deny the allegations contained in Paragraph 51 of Plaintiff's
14 Complaint.

15 52. Defendants deny the allegations contained in Paragraph 52 of Plaintiff's
16 Complaint.

17 53. Defendants are without knowledge or information sufficient to form a belief as
18 to the truth of the allegations regarding the trade name of any inferior vena cava filter
19 implanted in Plaintiff and, on that basis, deny them. Defendants deny any remaining
20 allegations of Paragraph 53 of Plaintiff's Complaint.

21 54. Defendants are without knowledge or information sufficient to form a belief as
22 to the truth of the allegations regarding the trade name of any inferior vena cava filter
23 implanted in Plaintiff and, on that basis, deny them. By way of further response, Defendants
24 admit that Bard owns a facility where vena cava filters are manufactured and that filters under
25 the trademark Eclipse™ Filter System were manufactured at that facility. Defendants further
26 admit that BPV designs, sells, markets, and distributes inferior vena cava filters and that BPV
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1 designed, sold, marketed, and distributed filters under the trademark Eclipse™ Filter System.
2 Defendants deny any remaining allegations of Paragraph 54 of Plaintiff's Complaint.

3 55. Defendants deny the allegations contained in Paragraph 55 of Plaintiff's
4 Complaint.

5 56. Defendants deny the allegations contained in Paragraph 56 of Plaintiff's
6 Complaint.

7 57. Defendants deny the allegations contained in Paragraph 57 of Plaintiff's
8 Complaint.

9 58. Defendants deny the allegations contained in Paragraph 58 of Plaintiff's
10 Complaint.

11 59. Defendants deny the allegations contained in Paragraph 59 of Plaintiff's
12 Complaint.

13 60. Defendants deny the allegations contained in Paragraph 60 of Plaintiff's
14 Complaint.

15 61. Defendants deny the allegations contained in Paragraph 61 of Plaintiff's
16 Complaint.

17 62. Defendants deny the allegations contained in Paragraph 62 of Plaintiff's
18 Complaint.

19 63. Defendants deny the allegations contained in Paragraph 63 of Plaintiff's
20 Complaint.

21 **COUNT I**

22 **NEGLIGENCE AS TO BARD**

23 64. Defendants incorporate by reference their responses to Paragraphs 1-63 of
24 Plaintiff's Complaint as if fully set forth herein.

25 65. Defendants deny the allegations contained in Paragraph 65 of Plaintiff's
26 Complaint as stated. By way of further response, Defendants admit that Bard owns a facility
27 where vena cava filters are manufactured and that filters under the trademarks Recovery®,
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1 G2®, and Eclipse™ Filter Systems were manufactured at that facility. Defendants further
2 admit that BPV designs, sells, markets, and distributes inferior vena cava filters and that BPV
3 designed, sold, marketed, and distributed filters under the trademarks Recovery®, G2®, and
4 Eclipse™ Filter Systems. Defendants deny any remaining allegations contained in
5 Paragraph 65 of Plaintiff's Complaint.

6 66. Defendants are without knowledge or information sufficient to form a belief as
7 to the truth of the allegations regarding the trade name of any inferior vena cava filter
8 implanted in Plaintiff and, on that basis, deny them. Defendants deny any remaining
9 allegations of Paragraph 66 of Plaintiff's Complaint.

10 67. The allegations contained in Paragraph 67 regarding Defendants' duty are
11 conclusions of law, and no answer is required. To the extent a response is required,
12 Defendants deny the allegations. Defendants deny the remaining allegations contained in
13 Paragraph 67 of Plaintiff's Complaint.

14 68. Defendants deny the allegations contained in Paragraph 68 of Plaintiff's
15 Complaint.

16 69. Defendants deny the allegations contained in Paragraph 69 of Plaintiff's
17 Complaint, including all sub-parts thereof.

18 70. Defendants deny the allegations contained in Paragraph 70 of Plaintiff's
19 Complaint.

20 71. Defendants deny the allegations contained in Paragraph 71 of Plaintiff's
21 Complaint.

22 72. Defendants deny the allegations contained in Paragraph 72 of Plaintiff's
23 Complaint, including all sub-parts thereof.

24 73. Defendants deny the allegations contained in Paragraph 73 of Plaintiff's
25 Complaint.

COUNT II**NEGLIGENT FAILURE TO WARN AS TO BARD**

74. Defendants incorporate by reference their responses to Paragraphs 1-73 of Plaintiff's Complaint as if fully set forth herein.

75. Defendants admit that Bard owns a facility where vena cava filters are manufactured and that filters under the trademark Eclipse™ Filter System were manufactured at that facility. Defendants further admit that BPV designs, sells, markets, and distributes inferior vena cava filters and that BPV designed, sold, marketed, and distributed filters under the trademark Eclipse™ Filter System. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding the trade name of any inferior vena cava filter implanted in Plaintiff and, on that basis, deny them. Defendants deny any remaining allegations contained in Paragraph 75 of Plaintiff's Complaint.

76. Defendants deny the allegations contained in Paragraph 76 of Plaintiff's Complaint.

77. The allegations contained in Paragraph 77 regarding Defendants' duty are conclusions of law, and no answer is required. To the extent a response is required, Defendants deny the allegations. Defendants deny the remaining allegations contained in Paragraph 77 of Plaintiff's Complaint.

78. Defendants deny the allegations contained in Paragraph 78 of Plaintiff's Complaint.

79. Defendants deny the allegations contained in Paragraph 79 of Plaintiff's Complaint.

80. Defendants deny the allegations contained in Paragraph 80 of Plaintiff's Complaint.

81. Defendants deny the allegations contained in Paragraph 81 of Plaintiff's Complaint.

82. Defendants deny the allegations contained in Paragraph 82 of Plaintiff's Complaint.

83. Defendants deny the allegations contained in Paragraph 83 of Plaintiff's Complaint.

84. Defendants deny the allegations contained in Paragraph 84 of Plaintiff's Complaint.

COUNT III

STRICT LIABILITY FAILURE TO WARN

85. Defendants incorporate by reference their responses to Paragraphs 1-84 of Plaintiff's Complaint as if fully set forth herein.

86. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding the trade name of any inferior vena cava filter implanted in Plaintiff and, on that basis, deny them. By way of further response, Defendants admit that Bard owns a facility where vena cava filters are manufactured and that filters under the trademark Eclipse™ Filter System were manufactured at that facility. Defendants further admit that BPV designs, sells, markets, and distributes inferior vena cava filters and that BPV designed, sold, marketed, and distributed filters under the trademark Eclipse™ Filter System. Defendants deny any remaining allegations contained in Paragraph 86 of Plaintiff's Complaint.

87. Defendants deny the allegations contained in Paragraph 87 of Plaintiff's Complaint.

88. The allegations contained in Paragraph 88 regarding Defendants' duty are legal conclusions of law, and no answer is required. To the extent a response is required, Defendants deny the allegations. Defendants deny any remaining allegations contained in Paragraph 88 of Plaintiff's Complaint.

89. Defendants deny the allegations contained in Paragraph 89 of Plaintiff's Complaint.

90. Defendants deny the allegations contained in Paragraph 90 of Plaintiff's Complaint.

91. Defendants deny the allegations contained in Paragraph 91 of Plaintiff's Complaint.

92. Defendants deny the allegations contained in Paragraph 92 of Plaintiff's Complaint.

93. Defendants deny the allegations contained in Paragraph 93 of Plaintiff's Complaint.

94. Defendants deny the allegations contained in Paragraph 94 of Plaintiff's Complaint.

95. Defendants deny the allegations contained in Paragraph 95 of Plaintiff's Complaint.

COUNT IV

STRICT LIABILITY DESIGN DEFECT

96. Defendants incorporate by reference their responses to Paragraphs 1-95 of Plaintiff's Complaint as if fully set forth herein.

97. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding the trade name of any inferior vena cava filter implanted in Plaintiff and, on that basis, deny them. By way of further response, Defendants admit that Bard owns a facility where vena cava filters are manufactured and that filters under the trademark Eclipse™ Filter System were manufactured at that facility. Defendants further admit that BPV designs, sells, markets, and distributes inferior vena cava filters and that BPV designed, sold, marketed, and distributed filters under the trademark Eclipse™ Filter System. Defendants deny any remaining allegations contained in Paragraph 97 of Plaintiff's Complaint.

98. Defendants deny the allegations contained in Paragraph 98 of Plaintiff's Complaint.

99. Defendants deny the allegations contained in Paragraph 99 of Plaintiff's Complaint.

100. Defendants deny the allegations contained in Paragraph 100 of Plaintiff's Complaint.

101. Defendants deny the allegations contained in Paragraph 101 of Plaintiff's Complaint.

102. Defendants deny the allegations contained in Paragraph 102 of Plaintiff's Complaint.

103. Defendants deny the allegations contained in Paragraph 103 of Plaintiff's Complaint.

COUNT V

STRICT LIABILITY MANUFACTURING DEFECT

104. Defendants incorporate by reference their responses to Paragraphs 1-103 of Plaintiff's Complaint as if fully set forth herein.

105. Defendants deny the allegations contained in Paragraph 105 of Plaintiff's Complaint.

106. Defendants deny the allegations contained in Paragraph 106 of Plaintiff's Complaint.

107. Defendants deny the allegations contained in Paragraph 107 of Plaintiff's Complaint.

108. Defendants deny the allegations contained in Paragraph 108 of Plaintiff's Complaint.

109. Defendants deny the allegations contained in Paragraph 109 of Plaintiff's Complaint.

COUNT VI

BREACH OF EXPRESS WARRANTY OF MERCHANTABILITY

110. Defendants incorporate by reference their responses to Paragraphs 1-109 of Plaintiff's Complaint as if fully set forth herein.

111. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding the trade name of any inferior vena cava filter implanted in Plaintiff and, on that basis, deny them. By way of further response, Defendants admit that Bard owns a facility where vena cava filters are manufactured and that filters under the trademark Eclipse™ Filter System were manufactured at that facility. Defendants further admit that BPV designs, sells, markets, and distributes inferior vena cava filters and that BPV designed, sold, marketed, and distributed filters under the trademark Eclipse™ Filter System. Defendants deny any remaining allegations contained in Paragraph 111 of Plaintiff's Complaint.

112. Defendants deny the allegations contained in Paragraph 112 of Plaintiff's Complaint.

113. Defendants deny the allegations contained in Paragraph 113 of Plaintiff's Complaint.

114. Defendants deny the allegations contained in Paragraph 114 of Plaintiff's Complaint.

115. Defendants deny the allegations contained in Paragraph 115 of Plaintiff's Complaint.

116. Defendants deny the allegations contained in Paragraph 116 of Plaintiff's Complaint, including all sub-parts thereof.

117. Defendants deny the allegations contained in Paragraph 117 of Plaintiff's Complaint.

118. Defendants deny the allegations contained in Paragraph 118 of Plaintiff's Complaint.

1 119. Defendants deny the allegations contained in Paragraph 119 of Plaintiff's
2 Complaint.

3 120. Defendants deny the allegations contained in Paragraph 120 of Plaintiff's
4 Complaint.

5 **COUNT VII**

6 **BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY**

7 121. Defendants incorporate by reference their responses to Paragraphs 1-120 of
8 Plaintiff's Complaint as if fully set forth herein.

9 122. Defendants admit that Bard owns a facility where vena cava filters are
10 manufactured and that filters under the trademark Eclipse™ Filter System were manufactured
11 at that facility. Defendants further admit that BPV designs, sells, markets, and distributes
12 inferior vena cava filters and that BPV designed, sold, marketed, and distributed filters under
13 the trademark Eclipse™ Filter System. Defendants deny any remaining allegations contained
14 in Paragraph 122 of Plaintiff's Complaint.

15 123. Defendants deny the allegations contained in Paragraph 123 of Plaintiff's
16 Complaint.

17 124. Defendants deny the allegations contained in Paragraph 124 of Plaintiff's
18 Complaint.

19 125. Defendants deny the allegations contained in Paragraph 125 of Plaintiff's
20 Complaint.

21 126. Defendants deny the allegations contained in Paragraph 126 of Plaintiff's
22 Complaint, including all sub-parts thereof.

23 127. Defendants deny the allegations contained in Paragraph 127 of Plaintiff's
24 Complaint.

25 128. Defendants deny the allegations contained in Paragraph 128 of Plaintiff's
26 Complaint.

1 129. Defendants deny the allegations contained in Paragraph 129 of Plaintiff's
2 Complaint.

3 130. Defendants deny the allegations contained in Paragraph 130 of Plaintiff's
4 Complaint.

5 **COUNT VIII**

6 **BREACH OF IMPLIED WARRANTY OF**
7 **FITNESS FOR A PARTICULAR PURPOSE**

8 131. Defendants incorporate by reference their responses to Paragraphs 1-130 of
9 Plaintiff's Complaint as if fully set forth herein.

10 132. Defendants admit that Bard owns a facility where vena cava filters are
11 manufactured and that filters under the trademark Eclipse™ Filter System were manufactured
12 at that facility. Defendants further admit that BPV designs, sells, markets, and distributes
13 inferior vena cava filters and that BPV designed, sold, marketed, and distributed filters under
14 the trademark Eclipse™ Filter System. Defendants deny any remaining allegations contained
15 in Paragraph 132 of Plaintiff's Complaint.

16 133. Defendants deny the allegations contained in Paragraph 133 of Plaintiff's
17 Complaint.

18 134. Defendants deny the allegations contained in Paragraph 134 of Plaintiff's
19 Complaint.

20 135. Defendants deny the allegations contained in Paragraph 135 of Plaintiff's
21 Complaint.

22 136. Defendants deny the allegations contained in Paragraph 136 of Plaintiff's
23 Complaint, including all sub-parts thereof.

24 137. Defendants deny the allegations contained in Paragraph 137 of Plaintiff's
25 Complaint.

26 138. Defendants deny the allegations contained in Paragraph 138 of Plaintiff's
27 Complaint.

1 139. Defendants deny the allegations contained in Paragraph 139 of Plaintiff's
2 Complaint.

3 140. Defendants deny the allegations contained in Paragraph 140 of Plaintiff's
4 Complaint.

5 **COUNT IX**

6 **FRAUDULENT CONCEALMENT**

7 141. Defendants incorporate by reference their responses to Paragraphs 1-140 of
8 Plaintiff's Complaint as if fully set forth herein.

9 142. Defendants deny the allegations contained in Paragraph 142 of Plaintiff's
10 Complaint.

11 143. Defendants deny the allegations contained in Paragraph 143 of Plaintiff's
12 Complaint.

13 144. Defendants deny the allegations contained in Paragraph 144 of Plaintiff's
14 Complaint.

15 145. Defendants deny the allegations contained in Paragraph 145 of Plaintiff's
16 Complaint.

17 146. Defendants deny the allegations contained in Paragraph 146 of Plaintiff's
18 Complaint.

19 147. Defendants deny the allegations contained in Paragraph 147 of Plaintiff's
20 Complaint.

21 **COUNT X**

22 **NEGLIGENT MISREPRESENTATION**

23 148. Defendants incorporate by reference their responses to Paragraphs 1-147 of
24 Plaintiff's Complaint as if fully set forth herein.

25 149. Defendants deny the allegations contained in Paragraph 149 of Plaintiff's
26 Complaint, including all sub-parts thereof.

150. Defendants deny the allegations contained in Paragraph 150 of Plaintiff's Complaint.

151. Defendants deny the allegations contained in Paragraph 151 of Plaintiff's Complaint.

152. Defendants deny the allegations contained in Paragraph 152 of Plaintiff's Complaint.

153. Defendants deny the allegations contained in Paragraph 153 of Plaintiff's Complaint.

154. Defendants deny the allegations contained in Paragraph 154 of Plaintiff's Complaint.

155. Defendants deny the allegations contained in Paragraph 155 of Plaintiff's Complaint.

156. Defendants deny the allegations contained in Paragraph 156 of Plaintiff's Complaint.

157. Defendants deny the allegations contained in Paragraph 157 of Plaintiff's Complaint.

158. Defendants deny the allegations contained in Paragraph 158 of Plaintiff's Complaint.

159. Defendants deny the allegations contained in Paragraph 159 of Plaintiff's Complaint.

160. Defendants deny the allegations contained in Paragraph 160 of Plaintiff's Complaint.

COUNT XI

FRAUDULENT MISREPRESENTATION

161. Defendants incorporate by reference their responses to Paragraphs 1-160 of Plaintiff's Complaint as if fully set forth herein.

1 162. Defendants deny the allegations contained in Paragraph 162 of Plaintiff's
2 Complaint, including all sub-parts thereof.

3 163. Defendants deny the allegations contained in Paragraph 163 of Plaintiff's
4 Complaint.

5 164. Defendants deny the allegations contained in Paragraph 164 of Plaintiff's
6 Complaint.

7 165. Defendants deny the allegations contained in Paragraph 165 of Plaintiff's
8 Complaint.

9 166. Defendants deny the allegations contained in Paragraph 166 of Plaintiff's
10 Complaint.

11 167. Defendants deny the allegations contained in Paragraph 167 of Plaintiff's
12 Complaint.

13 168. Defendants deny the allegations contained in Paragraph 168 of Plaintiff's
14 Complaint.

15 169. Defendants deny the allegations contained in Paragraph 169 of Plaintiff's
16 Complaint.

17 170. Defendants deny the allegations contained in Paragraph 170 of Plaintiff's
18 Complaint.

19 171. Defendants deny the allegations contained in Paragraph 171 of Plaintiff's
20 Complaint.

21 172. Defendants deny the allegations contained in Paragraph 172 of Plaintiff's
22 Complaint.

23 **PUNITIVE DAMAGES ALLEGATIONS**

24 173. Defendants incorporate by reference their responses to Paragraphs 1-172 of
25 Plaintiff's Complaint as if fully set forth herein.

26 174. Defendants deny the allegations contained in Paragraph 174 of Plaintiff's
27 Complaint.

1 175. Defendants deny the allegations contained in Paragraph 175 of Plaintiff's
2 Complaint, including all sub-parts thereof.

3 176. Defendants deny the allegations contained in Paragraph 176 of Plaintiff's
4 Complaint.

5 177. Defendants deny the allegations contained in Paragraph 177 of Plaintiff's
6 Complaint.

7 **PRAYER FOR DAMAGES**

8 Furthermore, responding to the unnumbered Paragraph, including sub-parts numbered
9 Paragraphs 178-181, following the heading "PRAYER FOR DAMAGES" and beginning
10 "WHEREFORE," Defendants deny the allegations contained in such Paragraph and sub-
11 parts.

12 178. Defendants deny the allegations contained in Paragraph 178 of Plaintiff's
13 Complaint and deny that Plaintiff is entitled to any relief requested in Plaintiff's Complaint.

14 179. Defendants deny the allegations contained in Paragraph 179 of Plaintiff's
15 Complaint and deny that Plaintiff is entitled to any relief requested in Plaintiff's Complaint.

16 180. Defendants deny the allegations contained in Paragraph 180 of Plaintiff's
17 Complaint and deny that Plaintiff is entitled to any relief requested in Plaintiff's Complaint.

18 181. Defendants deny the allegations contained in Paragraph 181 of Plaintiff's
19 Complaint and deny that Plaintiff is entitled to any relief requested in Plaintiff's Complaint.

20 182. Defendants deny the allegations contained in Paragraph 182 of Plaintiff's
21 Complaint and deny that Plaintiff is entitled to any relief requested in Plaintiff's Complaint.

22 183. Defendants deny the allegations contained in Paragraph 183 of Plaintiff's
23 Complaint and deny that Plaintiff is entitled to any relief requested in Plaintiff's Complaint.

24 184. Defendants deny the allegations contained in Paragraph 184 of Plaintiff's
25 Complaint and deny that Plaintiff is entitled to any relief requested in Plaintiff's Complaint.

26 185. Defendants deny the allegations contained in Paragraph 185 of Plaintiff's
27 Complaint and deny that Plaintiff is entitled to any relief requested in Plaintiff's Complaint.
28

1 186. Defendants deny the allegations contained in Paragraph 186 of Plaintiff's
2 Complaint and deny that Plaintiff is entitled to any relief requested in Plaintiff's Complaint.

3 187. Defendants deny the allegations contained in Paragraph 187 of Plaintiff's
4 Complaint and deny that Plaintiff is entitled to any relief requested in Plaintiff's Complaint.

5 188. Defendants deny the allegations contained in Paragraph 188 of Plaintiff's
6 Complaint and deny that Plaintiff is entitled to any relief requested in Plaintiff's Complaint.

7 189. Defendants deny the allegations contained in Paragraph 189 of Plaintiff's
8 Complaint and deny that Plaintiff is entitled to any relief requested in Plaintiff's Complaint.

9 190. Defendants deny the allegations contained in Paragraph 190 of Plaintiff's
10 Complaint and deny that Plaintiff is entitled to any relief requested in Plaintiff's Complaint.

11 191. Defendants deny the allegations contained in Paragraph 191 of Plaintiff's
12 Complaint and deny that Plaintiff is entitled to any relief requested in Plaintiff's Complaint.

13 192. Defendants deny the allegations contained in Paragraph 192 of Plaintiff's
14 Complaint and deny that Plaintiff is entitled to any relief requested in Plaintiff's Complaint.

15 193. Defendants deny the allegations contained in Paragraph 193 of Plaintiff's
16 Complaint and deny that Plaintiff is entitled to any relief requested in Plaintiff's Complaint.

17 194. Defendants deny the allegations contained in Paragraph 194 of Plaintiff's
18 Complaint and deny that Plaintiff is entitled to any relief requested in Plaintiff's Complaint.

19 195. Defendants deny the allegations contained in Paragraph 195 of Plaintiff's
20 Complaint and deny that Plaintiff is entitled to any relief requested in Plaintiff's Complaint.

21 196. Defendants deny the allegations contained in Paragraph 196 of Plaintiff's
22 Complaint and deny that Plaintiff is entitled to any relief requested in Plaintiff's Complaint.

23 197. Defendants deny the allegations contained in Paragraph 197 of Plaintiff's
24 Complaint and deny that Plaintiff is entitled to any relief requested in Plaintiff's Complaint.

25 198. Defendants deny the allegations contained in Paragraph 198 of Plaintiff's
26 Complaint and deny that Plaintiff is entitled to any relief requested in Plaintiff's Complaint.

1 199. Defendants deny the allegations contained in Paragraph 199 of Plaintiff's
2 Complaint and deny that Plaintiff is entitled to any relief requested in Plaintiff's Complaint.

3 200. Defendants deny the allegations contained in Paragraph 200 of Plaintiff's
4 Complaint and deny that Plaintiff is entitled to any relief requested in Plaintiff's Complaint.

5 201. Defendants deny the allegations contained in Paragraph 201 of Plaintiff's
6 Complaint and deny that Plaintiff is entitled to any relief requested in Plaintiff's Complaint.

7 202. Defendants deny the allegations contained in Paragraph 202 of Plaintiff's
8 Complaint and deny that Plaintiff is entitled to any relief requested in Plaintiff's Complaint.

9 203. Defendants deny the allegations contained in Paragraph 203 of Plaintiff's
10 Complaint and deny that Plaintiff is entitled to any relief requested in Plaintiff's Complaint.

11 204. Defendants deny the allegations contained in Paragraph 204 of Plaintiff's
12 Complaint and deny that Plaintiff is entitled to any relief requested in Plaintiff's Complaint.

13 205. Defendants deny the allegations contained in Paragraph 205 of Plaintiff's
14 Complaint and deny that Plaintiff is entitled to any relief requested in Plaintiff's Complaint.

15 206. Defendants deny the allegations contained in Paragraph 206 of Plaintiff's
16 Complaint and deny that Plaintiff is entitled to any relief requested in Plaintiff's Complaint.

17 207. Defendants deny the allegations contained in Paragraph 207 of Plaintiff's
18 Complaint and deny that Plaintiff is entitled to any relief requested in Plaintiff's Complaint.

19 208. Defendants deny the allegations contained in Paragraph 208 of Plaintiff's
20 Complaint and deny that Plaintiff is entitled to any relief requested in Plaintiff's Complaint.

21 209. Defendants deny the allegations contained in Paragraph 209 of Plaintiff's
22 Complaint and deny that Plaintiff is entitled to any relief requested in Plaintiff's Complaint.

23 210. Defendants deny the allegations contained in Paragraph 210 of Plaintiff's
24 Complaint and deny that Plaintiff is entitled to any relief requested in Plaintiff's Complaint.

25 211. Defendants deny the allegations contained in Paragraph 211 of Plaintiff's
26 Complaint and deny that Plaintiff is entitled to any relief requested in Plaintiff's Complaint.

1 212. Defendants deny the allegations contained in Paragraph 212 of Plaintiff's
2 Complaint and deny that Plaintiff is entitled to any relief requested in Plaintiff's Complaint.

3 213. Defendants deny the allegations contained in Paragraph 213 of Plaintiff's
4 Complaint and deny that Plaintiff is entitled to any relief requested in Plaintiff's Complaint.

5 214. Defendants deny the allegations contained in Paragraph 214 of Plaintiff's
6 Complaint and deny that Plaintiff is entitled to any relief requested in Plaintiff's Complaint.

7 215. Defendants deny the allegations contained in Paragraph 215 of Plaintiff's
8 Complaint and deny that Plaintiff is entitled to any relief requested in Plaintiff's Complaint.

9 216. Defendants deny the allegations contained in Paragraph 216 of Plaintiff's
10 Complaint and deny that Plaintiff is entitled to any relief requested in Plaintiff's Complaint.

11 217. Defendants deny the allegations contained in Paragraph 217 of Plaintiff's
12 Complaint and deny that Plaintiff is entitled to any relief requested in Plaintiff's Complaint.

13 218. Defendants deny the allegations contained in Paragraph 218 of Plaintiff's
14 Complaint and deny that Plaintiff is entitled to any relief requested in Plaintiff's Complaint.

15 219. Defendants deny the allegations contained in Paragraph 219 of Plaintiff's
16 Complaint and deny that Plaintiff is entitled to any relief requested in Plaintiff's Complaint.

17 220. Defendants deny the allegations contained in Paragraph 220 of Plaintiff's
18 Complaint and deny that Plaintiff is entitled to any relief requested in Plaintiff's Complaint.

19 221. Defendants deny the allegations contained in Paragraph 221 of Plaintiff's
20 Complaint and deny that Plaintiff is entitled to any relief requested in Plaintiff's Complaint.

21 222. Defendants deny the allegations contained in Paragraph 222 of Plaintiff's
22 Complaint and deny that Plaintiff is entitled to any relief requested in Plaintiff's Complaint.

23 223. Defendants deny the allegations contained in Paragraph 223 of Plaintiff's
24 Complaint and deny that Plaintiff is entitled to any relief requested in Plaintiff's Complaint.

25 224. Defendants deny the allegations contained in Paragraph 224 of Plaintiff's
26 Complaint and deny that Plaintiff is entitled to any relief requested in Plaintiff's Complaint.

1 225. Defendants deny the allegations contained in Paragraph 225 of Plaintiff's
2 Complaint and deny that Plaintiff is entitled to any relief requested in Plaintiff's Complaint.

3 226. Defendants deny the allegations contained in Paragraph 226 of Plaintiff's
4 Complaint and deny that Plaintiff is entitled to any relief requested in Plaintiff's Complaint.

5 227. Defendants deny the allegations contained in Paragraph 227 of Plaintiff's
6 Complaint and deny that Plaintiff is entitled to any relief requested in Plaintiff's Complaint.

7 228. Defendants deny the allegations contained in Paragraph 228 of Plaintiff's
8 Complaint and deny that Plaintiff is entitled to any relief requested in Plaintiff's Complaint.

9 229. Defendants deny the allegations contained in Paragraph 229 of Plaintiff's
10 Complaint and deny that Plaintiff is entitled to any relief requested in Plaintiff's Complaint.

11 230. Defendants deny the allegations contained in Paragraph 230 of Plaintiff's
12 Complaint and deny that Plaintiff is entitled to any relief requested in Plaintiff's Complaint.

13 231. Defendants deny the allegations contained in Paragraph 231 of Plaintiff's
14 Complaint and deny that Plaintiff is entitled to any relief requested in Plaintiff's Complaint.

15 232. Defendants deny the allegations contained in Paragraph 232 of Plaintiff's
16 Complaint and deny that Plaintiff is entitled to any relief requested in Plaintiff's Complaint.

17 233. Defendants deny the allegations contained in Paragraph 233 of Plaintiff's
18 Complaint and deny that Plaintiff is entitled to any relief requested in Plaintiff's Complaint.

19 234. Defendants deny the allegations contained in Paragraph 234 of Plaintiff's
20 Complaint and deny that Plaintiff is entitled to any relief requested in Plaintiff's Complaint.

21 235. Defendants deny the allegations contained in Paragraph 235 of Plaintiff's
22 Complaint and deny that Plaintiff is entitled to any relief requested in Plaintiff's Complaint.

23 236. Defendants deny the allegations contained in Paragraph 236 of Plaintiff's
24 Complaint and deny that Plaintiff is entitled to any relief requested in Plaintiff's Complaint.

25 237. Defendants deny the allegations contained in Paragraph 237 of Plaintiff's
26 Complaint and deny that Plaintiff is entitled to any relief requested in Plaintiff's Complaint.

238. Defendants deny the allegations contained in Paragraph 238 of Plaintiff's Complaint and deny that Plaintiff is entitled to any relief requested in Plaintiff's Complaint.

239. Defendants deny the allegations contained in Paragraph 239 of Plaintiff's Complaint and deny that Plaintiff is entitled to any relief requested in Plaintiff's Complaint.

240. Defendants deny the allegations contained in Paragraph 240 of Plaintiff's Complaint and deny that Plaintiff is entitled to any relief requested in Plaintiff's Complaint.

Defendants further deny each and every allegation not specifically admitted herein.

DEFENSES

Defendants allege as affirmative defenses the following:

1. Plaintiff's Complaint filed herein fails to state a claim or claims upon which relief can be granted under Rule 12 of the Federal Rules of Civil Procedure.

2. The sole proximate cause of Plaintiff's damages, if any were sustained, was the negligence of a person or persons or entity for whose acts or omissions Defendants were and are in no way liable.

3. Plaintiff's claims are barred, in whole or in part, by the applicable statutes of limitations and/or statute of repose.

4. If Plaintiff has been damaged, which Defendants deny, any recovery by Plaintiff is barred to the extent Plaintiff voluntarily exposed herself to a known risk and/or failed to mitigate her alleged damages. To the extent Plaintiff has failed to mitigate her alleged damages, any recovery shall not include alleged damages that could have been avoided by reasonable care and diligence.

5. If Plaintiff has been damaged, which Defendants deny, such damages were caused by the negligence or fault of Plaintiff.

6. If Plaintiff has been damaged, which Defendants deny, such damages were caused by the negligence or fault of persons and/or entities for whose conduct Defendants are not legally responsible.

1 7. The conduct of Defendants and the subject product at all times conformed with
2 the Federal Food, Drug and Cosmetics Act, 21 U.S.C. § 301, *et seq.*, and other pertinent
3 federal statutes and regulations. Accordingly, Plaintiff's claims are barred, in whole or in
4 part, under the doctrine of federal preemption, and granting the relief requested would
5 impermissibly infringe upon and conflict with federal laws, regulations, and policies in
6 violation of the Supremacy Clause of the United States Constitution.

7 8. If Plaintiff has been damaged, which Defendants deny, such damages were
8 caused by unforeseeable, independent, intervening, and/or superseding events for which
9 Defendants are not legally responsible.

10 9. There was no defect in the product at issue with the result that Plaintiff is not
11 entitled to recover against Defendants in this cause.

12 10. If there were any defect in the products – and Defendants deny that there were
13 any defects – nevertheless, there was no causal connection between any alleged defect and
14 the product on the one hand and any damage to Plaintiff on the other with the result that
15 Plaintiff is not entitled to recover against Defendants in this cause.

16 11. Plaintiff's injuries, losses or damages, if any, were caused by or contributed to
17 by other persons or entities that are severally liable for all or part of Plaintiff's alleged
18 injuries, losses or damages. If Defendants are held liable to Plaintiff, which liability is
19 specifically denied, Defendants are entitled to contribution, set-off, and/or indemnification,
20 either in whole or in part, from all persons or entities whose negligence or fault proximately
21 caused or contributed to cause Plaintiff's alleged damages.

22 12. Plaintiff's claims are barred to the extent that the injuries alleged in the
23 Plaintiff's Complaint were caused by the abuse, misuse, abnormal use, or use of the product
24 at issue in a manner not intended by Defendants and over which Defendants had no control.

25 13. Plaintiff's claims are barred to the extent that the injuries alleged in the
26 Plaintiff's Complaint were caused by a substantial change in the product after leaving the
27 possession, custody, and control of Defendants.
28

1 14. Plaintiff's breach of warranty claims are barred because: (1) Defendants did
2 not make any warranties, express or implied, to Plaintiff; (2) there was a lack of privity
3 between Defendants and Plaintiff; and (3) notice of an alleged breach was not given to the
4 seller or Defendants.

5 15. Plaintiff's claims for breach of implied warranty must fail because the product
6 was not used for its ordinary purpose.

7 16. Defendants neither had nor breached any alleged duty to warn with respect to
8 the product, with the result that Plaintiff is not entitled to recover in this cause.

9 17. Plaintiff's claims are barred by Defendants' dissemination of legally adequate
10 warnings and instructions to learned intermediaries.

11 18. At all relevant times, herein, Plaintiff's physicians were in the position of
12 sophisticated purchasers, fully knowledgeable and informed with respect to the risks and
13 benefits of the subject product.

14 19. If Plaintiff has been damaged, which Defendants deny, the actions of persons or
15 entities for whose conduct Defendants are not legally responsible and the independent
16 knowledge of these persons or entities of the risks inherent in the use of the product and other
17 independent causes, constitute an intervening and superseding cause of Plaintiff's alleged
18 damages.

19 20. To the extent that injuries and damages sustained by Plaintiff, as alleged in
20 Plaintiff's Complaint, were caused directly, solely, and proximately by sensitivities, medical
21 conditions, and idiosyncrasies peculiar to Plaintiff not found in the general public, they were
22 unknown, unknowable, or not reasonably foreseeable to Defendants.

23 21. Defendants believe, and upon that ground allege, that Plaintiff was advised of
24 the risks associated with the matters alleged in Plaintiff's Complaint and knowingly and
25 voluntarily assumed them. Pursuant to the doctrine of assumption of the risk, informed
26 consent, release, waiver, or comparative fault, this conduct bars in whole or in part the
27 damages that Plaintiff seeks to recover herein.

1 22. At all relevant times during which the device at issue was designed, developed,
2 manufactured, and sold, the device was reasonably safe and reasonably fit for its intended
3 use, was not defective or unreasonably dangerous, and was accompanied by proper warnings,
4 information, and instructions, all pursuant to generally recognized prevailing industry
5 standards and state-of-the-art in existence at the time.

6 23. Plaintiff's claims are barred because Plaintiff suffered no injury or damages as a
7 result of the alleged conduct and do not have any right, standing, or competency to maintain
8 claims for damages or other relief.

9 24. Plaintiff's claims are barred, in whole or in part, by the doctrines of waiver,
10 estoppel, and/or laches.

11 25. If Plaintiff suffered any damages or injuries, which is denied, Defendants state
12 that Plaintiff's recovery is barred, in whole or in part, or subject to reduction, under the
13 doctrines of contributory and/or comparative negligence.

14 26. In the further alternative, and only in the event that it is determined that
15 Plaintiff is entitled to recover against Defendants, recovery should be reduced in proportion to
16 the degree or percentage of negligence, fault or exposure to products attributable to Plaintiff,
17 any other defendants, third-party defendants, or other persons, including any party immune
18 because bankruptcy renders them immune from further litigation, as well as any party, co-
19 defendant, or non-parties with whom Plaintiff has settled or may settle in the future.

20 27. Should Defendants be held liable to Plaintiff, which liability is specifically
21 denied, Defendants would be entitled to a setoff for the total of all amounts paid to Plaintiff
22 from all collateral sources.

23 28. Plaintiff's claims may be barred, in whole or in part, from seeking recovery
24 against Defendants pursuant to the doctrines of *res judicata*, collateral estoppel, release of
25 claims, and the prohibition on double recovery for the same injury.

1 29. The injuries and damages allegedly sustained by Plaintiff may be due to the
2 operation of nature or idiosyncratic reaction(s) and/or pre-existing condition(s) in Plaintiff
3 over which Defendants had no control.

4 30. The conduct of Defendants and all activities with respect to the subject product
5 have been and are under the supervision of the Federal Food and Drug Administration
6 (“FDA”). Accordingly, this action, including any claims for monetary and/or injunctive relief,
7 is barred by the doctrine of primary jurisdiction and exhaustion of administrative remedies.

8 31. Defendants assert any and all defenses, claims, credits, offsets, or remedies
9 provided by the Restatements (Second and Third) of Torts and reserve the right to amend
10 their Answer to file such further pleadings as are necessary to preserve and assert such
11 defenses, claims, credits, offsets, or remedies.

12 32. The device at issue complied with any applicable product safety statute or
13 administrative regulation, and therefore Plaintiff’s defective design and warnings-based
14 claims are barred under the Restatement (Third) of Torts: Products Liability § 4, et seq. and
15 comments thereto.

16 33. Plaintiff cannot show that any reasonable alternative design would have
17 rendered the Recovery® Filter inferior vena cava filter device as alleged in Plaintiff’s
18 Complaint to be safer overall under the Restatement (Third) of Product Liability § 2, cmt. f,
19 nor could Defendants have known of any alternative design that may be identified by
20 Plaintiff.

21 34. The device at issue was not sold in a defective condition unreasonably
22 dangerous to the user or consumer, and therefore Plaintiff’s claims are barred under the
23 Restatement (Second) of Torts: Products Liability § 402A and comments thereto, and
24 comparable provisions of the Restatement (Third) of Torts (Products Liability).

25 35. At all relevant times during which the device at issue was designed, developed,
26 manufactured, and sold, the device was reasonably safe and reasonably fit for its intended
27 use, was not defective or unreasonably dangerous, and was accompanied by proper warnings,
28

1 information, and instructions, all pursuant to generally recognized prevailing industry
2 standards and state-of-the-art in existence at the time.

3 36. Defendants specifically plead all affirmative defenses under the Uniform
4 Commercial Code (“UCC”) now existing or which may arise in the future, including those
5 defenses provided by UCC §§ 2-607 and 2-709.

6 37. Plaintiff’s alleged damages, if any, should be apportioned among all parties at
7 fault, and any non-parties at fault, pursuant to the Uniform Contribution Among Tortfeasors
8 Act.

9 38. No act or omission of Defendants was malicious, willful, wanton, reckless, or
10 grossly negligent, and, therefore, any award of punitive damages is barred.

11 39. To the extent the claims asserted in Plaintiff’s Complaint are based on a theory
12 providing for liability without proof of defect and proof of causation, the claims violate
13 Defendants’ rights under the Constitution of the United States and analogous provisions of
14 the Illinois Constitution.

15 40. Regarding Plaintiff’s demand for punitive damages, Defendants specifically
16 incorporate by reference any and all standards of limitations regarding the determination
17 and/or enforceability of punitive damages awards that arose in the decisions of *BMW of No.*
18 *America v. Gore*, 517 U.S. 559 (1996); *Cooper Industries, Inc. v. Leatherman Tool Group,*
19 *Inc.*, 532 U.S. 424 (2001); *State Farm Mut. Auto Ins. Co. v. Campbell*, 123 S. Ct. 1513
20 (2003); and *Exxon Shipping Co. v. Baker*, No. 07-219, 2008 U.S. LEXIS 5263 (U.S. June 25,
21 2008) and their progeny as well as other similar cases under both federal and state law.

22 41. Plaintiff’s claims for punitive or exemplary damages violate, and are therefore
23 barred by, the Fourth, Fifth, Sixth, Eighth and Fourteenth Amendments to the Constitution of
24 the United States of America, and similar provisions of the Illinois Constitution, on grounds
25 including the following:

- 26 (a) it is a violation of the Due Process and Equal Protection Clauses of the
27 Fourteenth Amendment of the United States Constitution to impose punitive
28

1 damages, which are penal in nature, against a civil defendant upon the plaintiffs
2 satisfying a burden of proof which is less than the “beyond a reasonable doubt”
3 burden of proof required in criminal cases;

4 (b) the procedures pursuant to which punitive damages are awarded may result in
5 the award of joint and several judgments against multiple defendants for
6 different alleged acts of wrongdoing, which infringes upon the Due Process and
7 Equal Protection Clauses of the Fourteenth Amendment of the United States
8 Constitution;

9 (c) the procedures to which punitive damages are awarded fail to provide a
10 reasonable limit on the amount of the award against Defendants, which thereby
11 violates the Due Process Clause of the Fourteenth Amendment of the United
12 States Constitution;

13 (d) the procedures pursuant to which punitive damages are awarded fail to provide
14 specific standards for the amount of the award of punitive damages which
15 thereby violates the Due Process Clause of the Fourteenth Amendment of the
16 United States Constitution;

17 (e) the procedures pursuant to which punitive damages are awarded result in the
18 imposition of different penalties for the same or similar acts, and thus violate
19 the Equal Protection Clause of the Fourteenth Amendment of the United States
20 Constitution;

21 (f) the procedures pursuant to which punitive damages are awarded permit the
22 imposition of punitive damages in excess of the maximum criminal fine for the
23 same or similar conduct, which thereby infringes upon the Due Process Clause
24 of the Fifth and Fourteenth Amendments and the Equal Protection Clause of the
25 Fourteenth Amendment of the United States Constitution;

(g) the procedures pursuant to which punitive damages are awarded permit the imposition of excessive fines in violation of the Eighth Amendment of the United States Constitution;

(h) the award of punitive damages to the plaintiff in this action would constitute a deprivation of property without due process of law; and

(i) the procedures pursuant to which punitive damages are awarded permit the imposition of an excessive fine and penalty.

42. Defendants expressly reserve the right to raise as an affirmative defense that Plaintiff has failed to join all parties necessary for a just adjudication of this action, should discovery reveal the existence of facts to support such defense.

43. Defendants reserve the right to raise such other affirmative defenses as may be available or apparent during discovery or as may be raised or asserted by other defendants in this case. Defendants have not knowingly or intentionally waived any applicable affirmative defense. If it appears that any affirmative defense is or may be applicable after Defendants have had the opportunity to conduct reasonable discovery in this matter, Defendants will assert such affirmative defense in accordance with the Federal Rules of Civil Procedure.

REQUEST FOR JURY TRIAL

Defendants C. R. Bard, Inc. and Bard Peripheral Vascular, Inc. demand a trial by jury on all issues appropriate for jury determination.

WHEREFORE, Defendants aver that Plaintiff is not entitled to the relief demanded in the Plaintiff's Complaint, and these Defendants, having fully answered, pray that this action against them be dismissed and that they be awarded their costs in defending this action and that they be granted such other and further relief as the Court deems just and appropriate.

(Signatures on Following Page)

1 This 16th day of November, 2015.

2
3 s/Richard B. North, Jr.
4 Richard B. North, Jr.
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22 **Attorney for Defendants C. R. Bard, Inc. and**
23 **Bard Peripheral Vascular, Inc.**
24
25
26
27
28

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on November 16, 2015, I electronically filed the foregoing with the Clerk of the Court by using the CM/ECF system which will send notification of such filing to all counsel of record.

s/Richard B. North, Jr.
Richard B. North, Jr.
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